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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,300	04/09/2001	Hans R. Brunner	SSM-487US	2492

23122 7590 04/19/2004

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3762	17

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 1/28/04 has been entered.

Response to Amendment

2. The Applicant amended independent claims 1 and 14 to overcome the rejection of record, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 112

3. Claims 1-12 and 14-30 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

In claim 1, the phrase "for stimulating the venous flow to the blood" is unclear, specifically it is unclear how "to the blood" is related to the other limitations of the claim.

In claim 14, the phrase "stimulates return of the venous blood flow" is awkward and unclear, specifically the word "flow".

Claim Rejections - 35 USC § 103

4. Claims 1, 2, 9-18, 21, 22 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view of Barak et al. (US 64). Gardner et al. disclose a medical appliance for intermittently pulsed compression of proximal joint and adjacent tissue of the human body to stimulate venous flow of the blood from the extremities.

As related to claim 1, the readily portable medical appliance for intermittent compression of human extremities, includes a cuff (14) with a single chamber (15) and a miniature pressure generator (21) (figure 1 and 1A; col. 1 @ 35-46; col. 3 @ 2-12 and 53-56). The width of the cuff in the direction of return is sized to be a rectangular or trapezoidal shape with lateral edges that converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elbow would be at most 25 centimeters (figures 1, 1A and 4; col. 4 @ 12-36).

As to the cuff pressure, the cuff pressure is selective and ranges between atmospheric/ deflated pressure levels to 200 mm Hg with a suggested peak pressure of at least 75 mm Hg (col. 3 @ 56-61; col. 3 @ 66 – col. 4 @ 5), read to be inclusive of the ranges of 20 mm Hg to 100 mm Hg, and 25 mm Hg to 80 mm Hg. The cuff inherently corresponds to a cuff used for blood pressure measurements, these cuff known in the are to operate at about 60 mm Hg. (See cited references) .

As related to claim 7, the controller actuates a pressure generator (21) to pressurize the cuff with a defined pressure amplitude and a defined repetition frequency (col. 3 @ 53 – col. 4 @ 8).

As related to claim 8, selective control of the pump enables the peak pressure, read as amplitude and the intervals between successive pulses, read as the repetition frequency to be varied (col. 3 @ 66 – col. 4 @ 8).

As related to claim 10, the chamber is filled at least every 20 seconds or three times a minute (col. 3 @ 66 – col. 4 @ 5).

As related to claim 11, the chamber is filled at least every 20 seconds or 15 times in five minutes (col. 3 @ 66 – col. 4 @ 5).

As related to claim 12, the cuff and pump can be uncoupled when the inlet 19 is disconnected from the pump and associated conduit (figure 1 and 1A and col. 3 @ 53-53).

As related to claim 13, the readily portable medical appliance for stimulating flow of body fluids, includes a cuff (14) with a single chamber (15) and a miniature pressure generator (21) (figure 1 and 1A; col. 1 @ 35-46; col. 3 @ 2-12 and 53-56). The width of the cuff in the direction of return is sized to be a rectangular or trapezoidal shape with lateral edges that converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elbow would be at most 25 centimeters (figures 1, 1A and 4; col. 4 @ 12-36).

As related to claim 14, the method to use the readily portable medical appliance for stimulating the flow of body fluid, includes applying a cuff (14) with a single chamber (15) to an extremity and intermittently pressurizing the cuff using a miniature pressure generator (21) (figure 1 and 1A; col. 1 @ 35-46; col. 3 @ 2-12 and 53-56). The width of the cuff in the direction of return is sized to be a rectangular or trapezoidal shape with lateral edges that converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge

as described to encircle a knee or elbow would be at most 25 centimeters (figures 1, 1A and 4; col. 4 @ 12-36).

As related to claim 15, the controller actuates a pressure generator (21) to pressurize the cuff with a defined pressure amplitude and a defined repetition frequency (col. 3 @ 53 – col. 4 @ 8).

As related to claim 16, selective control of the pump enables the peak pressure, read as amplitude and the intervals between successive pulses, read as the repetition frequency to be varied (col. 3 @ 66 – col. 4 @ 8).

As related to claim 17, the chamber is filled at least every 20 seconds or three times a minute (col. 3 @ 66 – col. 4 @ 5).

As related to claim 18, the chamber is filled at least every 20 seconds or 15 times in five minutes (col. 3 @ 66 – col. 4 @ 5).

As discussed in previous fourteen paragraphs of this action, Gardner et al. disclose the claimed invention except for the generator being secured to clothing (claims 1, 13, 14, 21 and 22) and the cuff is attached to the calf (claim 30).

Barak et al. teaches a calf wrap for pneumatic compression using a miniature pressure generator secured to clothing, a belt, for the purpose enabling the patient to gain uninterrupted compression treatments while enjoying freedom of movement. It would have been obvious to one having ordinary skill in the art at the time of the invention to have secured a miniature pressure generator to clothing to compress the calf in the Gardner et al. system in order to create

a flexible, comfortable, light-weight system that accommodates the need for movement while enabling consistent compression treatments to the calf of the body so the treated condition improves as rapidly as possible and is effectively maintained at an optimum level (figure 1; col. 2 @ 19-29 and 41-65).

The Applicant arguments files 1/28/04 have been fully considered, but they are not convincing. The Applicant asserts Gardner et al. teach pressures of 200-220 mm Hg are required to effectuate venous-return flow. The Examiner disagrees. As discussed above, Gardner teaches pressures in the range of 60 mm Hg and in some applications up to 220 mm Hg are required to effectuate venous-return flow, hence teaching the claimed invention of pressure between 20 mm Hg and 100 mm Hg, namely 60 mm Hg to 100 mm Hg (col. 3 @ 56-61; col. 3 @ 66 – col. 4 @ 5).

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view of Barak et al. (US 6494852) and further in view of Raines et al. (US 6152881). As discussed in paragraph 4 of this action, modified Gardner et al. disclose the claimed invention except for the pressure generator being a roller pump.

Raines et al. disclose a method to characterize blood flow using a blood pressure cuff and teach that it is known to pressurize the cuff using a positive displacement pump (101) (figure 4 and col. 15 @ 1-6). A roller pump is a type of positive displacement pump. Absent any teaching of criticality or unexpected results for the specific type of pump used, substitution of a positive displacement pump for a roller pump would have been an obvious design choice. Therefore it

would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical appliance as taught by modified Gardner et al., with the roller pump, as taught by Raines et al. to specify a type of pump known in the art that effectively pressurizes a blood pressure cuff.

6. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view or Barak et al. (US 6494852) in view of Harada et al. (US 4928701). As discussed in paragraph 4 of this action, modified Gardner et al. disclose the claimed invention except for:

- a pressure control means to connect the cuff to the atmosphere when the cuff is overpressured (claim 4),
- the pressure control means comprising an outlet valve / overpressure outlet forming an overpressure outlet (claim 5),
- the pressure control means comprising a restrictor in a conduit and a stopper as a function of the pressure in the inlet and outlet of the restrictor (claim 6), and
- a controller which switches the generator ON/OFF to pressurize the cuff (claim 7).

Harada et al. disclose a method and apparatus for monitoring blood pressure and teach that it is known to provide a controller that switches the generator ON/OFF to pressurize the cuff and to provide a pressure control means that contains an outlet valve / overpressure outlet, a restrictor in a conduit, and a stopper so the cuff is connected to the atmosphere when the cuff is overpressured. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical appliance as taught by modified

Gardner et al., with the following elements as taught by Harada et al.:

- a central processing unit (24), read as a component of the pressure control means, to connect the cuff (10) to the atmosphere when the cuff (10) is overpressured, read as when the pressure exceeds the peak pressure or the time period for inflation is exceeded (claim 4) to enable the pressure in the cuff to be rapid removed from the cuff preventing harm to the patient, (figure 1; col. 6 @ 7-10 and 16-25),
- an additional pressure control means component, a rapid deflation port (16b), read as the outlet valve / overpressure outlet (claim 5), to enable the pressure in the cuff to be rapid removed from the cuff preventing harm to the patient, (figure 1; col. 6 @ 7-10),
- further pressure control means components: a directional control valve (16), read as the restrictor, in a conduit (19) and the position selector in the control valve (16), read as a stopper (claim 6) to enable the selection by the controller to inflate or deflate the cuff (col. 5 @ 57 – col. 6 @ 10; col. 6 @ 16-25) and
- a controller (24) which switches the generator ON/OFF to pressurize the cuff (claim 7) to enable the cuff to be inflated and deflated (col. 6 @ 16-25) .

Drawings

7. Figures 1 (boxes 2, 4, 5) and figure 4 (boxes 1, 2, 20, 24, 25) are objected to under 37 CFR 1.83(a) because the rectangular boxes/ circles are not labeled as described in the specification. Specifically, for example, the "Controller" should be written inside box 5 of figure 1. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction

or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Correction is required.

Allowable Subject Matter

8. Claims 20 and 23-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Other Prior Art Cited

9. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure.

US 3552381 to Burns teaches blood pressure cuffs operate at 60 mm Hg. (col. 3 @ 71-75).

US 4862895 to Yamasawa et al. teach a roller pump can be used to pressurize a blood pressure cuff (col. 1 @ 54-61).

Statutory Basis

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
4/18/04

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Office Action Summary	Application No.	Applicant(s)	
	09/720,300	BRUNNER ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/28/04 (Amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 21, 22 and 27-30* is/are rejected.

7)☒ Claim(s) *20 and 23-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

FPO 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *16*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.